February 10, 2009

HOUSE BILL No. 1382

DIGEST OF HB 1382 (Updated February 4, 2009 7:50 pm - DI 77)

Citations Affected: IC 5-10; IC 12-15; IC 27-8; IC 27-13; noncode.

Synopsis: Insurance coverage for clinical trials. Requires coverage for certain services related to cancer clinical trials under a state employee health plan, the state Medicaid program, a policy of accident and sickness insurance, and a health maintenance organization contract.

Effective: July 1, 2009.

Welch, Brown C, Brown T

January 13, 2009, read first time and referred to Committee on Public Health.
February 10, 2009, amended, reported — Do Pass.

February 10, 2009

First Regular Session 116th General Assembly (2009)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2008 Regular Session of the General Assembly.

HOUSE BILL No. 1382

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-10-8-15 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 15. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "covered individual" means an individual entitled to coverage under a state employee health plan.

(d) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The drug or device that is under evaluation in a clinical trial.

(2) Items or services that are:

(A) provided solely for data collection and analysis and not in the direct clinical management of an individual enrolled in a clinical trial;

(B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or

(C) provided solely to determine eligibility of an individual for participation in a clinical trial.

(e) As used in this section, "state employee health plan" means one (1) of the following:

(1) A self-insurance program established under section 7(b) of

this chapter to provide group health coverage.

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

(f) A state employee plan that provides coverage for basic health care services may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the plan would provide coverage for the same routine care costs not incurred in a clinical trial.

(g) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the state employee plan, including treatment rendered by participating and nonparticipating providers.

(h) This section does not require the state employee plan to offer coverage for clinical trial services rendered by a participating provider under the state employee plan.

(i) This section does not prohibit the state employee plan from offering coverage for clinical trial services by a participating provider.

(j) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

(k) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(l) This section does not create any private right or cause of action for or on behalf of any new patient against a party that issues the state employee plan.

SECTION 2. IC 12-15-5-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 9. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective

as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The drug or device that is under evaluation in a clinical trial.

(2) Items or services that are:

(A) provided solely for data collection and analysis and not in the direct clinical management of an individual enrolled in a clinical trial;

(B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or

(C) provided solely to determine eligibility of an individual for participation in a clinical trial.

(d) The Medicaid program may not exclude coverage for routine care costs that are incurred in the course of a clinical trial

if the program would provide coverage for the same routine care costs not incurred in a clinical trial.

(e) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the Medicaid program, including treatment rendered by participating and nonparticipating providers.

(f) This section does not require the Medicaid program to offer coverage for clinical trial services rendered by a participating provider under the Medicaid program.

(g) This section does not prohibit the Medicaid program from offering coverage for clinical trial services by a participating provider.

(h) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

(i) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(j) This section does not create any private right or cause of action for or on behalf of any new patient against the state.

(k) The office shall apply to amend the state Medicaid plan if the office determines that an amendment is necessary to carry out this section.

SECTION 3. IC 27-8-25 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]:

Chapter 25. Coverage for Care Related to Clinical Trials

Sec. 1. As used in this chapter, "care method" means the use of a particular drug or device in a particular manner.

Sec. 2. As used in this chapter, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

Sec. 3. As used in this chapter, "covered individual" means an individual entitled to coverage under a policy of accident and sickness insurance.

Sec. 4. As used in this chapter, "policy of accident and sickness insurance" has the meaning set forth in IC 27-8-5-1. The term does not include the following:

(1) Accident only, credit, dental, vision, Medicare, Medicare supplement, long term care, or disability income insurance.

(2) Coverage issued as a supplement to liability insurance.

(3) Automobile medical payment insurance.

(4) A specified disease policy.

(5) A limited benefit health insurance policy.

(6) A short term insurance plan that:

(A) may not be renewed; and

(B) has a duration of not more than six (6) months.

(7) A policy that provides a stipulated daily, weekly, or monthly payment to an insured during hospital confinement,

without regard to the actual expense of the confinement.

(8) Worker's compensation or similar insurance.

(9) A student health insurance policy.

Sec. 5. As used in this chapter, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The health care service, item, or investigational drug that is the subject of the clinical trial.

(2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.

(3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

(4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.

(5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the clinical trial.

(6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.

Sec. 6. (a) A policy of accident and sickness insurance may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the policy of accident and sickness insurance would provide coverage for the same routine care costs not incurred in a clinical trial.

(b) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the policy of accident and sickness insurance, including treatment rendered by participating and nonparticipating providers.

(c) This section does not require an insurer to offer coverage for clinical trial services rendered by a participating provider under a policy of accident and sickness insurance.

(d) This section does not prohibit an insurer from offering coverage for clinical trial services by a participating provider.

(e) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

Sec. 7. (a) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(b) This section does not create any private right or cause of action for or on behalf of any new patient against an insurer that issues a policy of accident and sickness insurance.

SECTION 4. IC 27-13-7-20 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 20. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(vi) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(vii) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The drug or device that is under evaluation in a clinical trial.

(2) Items or services that are:

(A) provided solely for data collection and analysis and not in the direct clinical management of an individual enrolled in a clinical trial;

(B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or

(C) provided solely to determine eligibility of an individual for participation in a clinical trial.

(d) An individual or a group contract that provides for basic health care services may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the contract would provide coverage for the same routine care costs not incurred in a clinical trial.

(e) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the individual or a group contract, including treatment rendered by participating and nonparticipating providers.

(f) This section does not require a health maintenance organization to offer coverage for clinical trial services rendered by a participating provider under an individual or a group contract.

(g) This section does not prohibit a health maintenance organization from offering coverage for clinical trial services by a participating provider.

(h) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

(i) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(j) This section does not create any private right or cause of action for or on behalf of any new patient against a health maintenance organization that issues an individual or a group contract.

SECTION 5. [EFFECTIVE JULY 1, 2009] **(a) IC 5-10-8-15, as added by this act, applies to a state employee health plan that is established, entered into, issued, delivered, amended, or renewed after June 30, 2009.**

(b) IC 12-15-5-9, as added by this act, applies to a Medicaid risk based managed care contract that is entered into, delivered, amended, or renewed after June 30, 2009.

(c) IC 27-8-25, as added by this act, applies to a policy of accident and sickness insurance that is issued, delivered, amended, or renewed after June 30, 2009.

(d) IC 27-13-7-20, as added by this act, applies to an individual contract or a group contract that is entered into, delivered, amended, or renewed after June 30, 2009.

(e) This SECTION expires July 1, 2014.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1382, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 1, line 9, delete "or another serious or life threatening disease".

Page 2, line 9, delete "or other serious or" and insert "**; and**

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 2, delete lines 10 through 31.

Page 3, delete lines 12 through 15, begin a new paragraph and insert:

"**(f) A state employee plan that provides coverage for basic health care services may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the plan would provide coverage for the same routine care costs not incurred in a clinical trial.**

(g) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the state employee plan, including treatment rendered by participating and nonparticipating providers.

(h) This section does not require the state employee plan to offer coverage for clinical trial services rendered by a participating provider under the state employee plan.

(i) This section does not prohibit the state employee plan from offering coverage for clinical trial services by a participating provider.

(j) This section does not require reimbursement for services that

are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

(k) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(l) This section does not create any private right or cause of action for or on behalf of any new patient against a party that issues the state employee plan.".

Page 3, line 24, delete "or another serious or life threatening disease".

Page 3, line 41, delete "or other serious or" and insert "**; and**".

Page 3, delete line 42.

Page 4, delete lines 1 through 21, begin a new line block indented and insert:

"**(2) that is approved or funded by one (1) of the following:**

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 4, delete lines 36 through 38, begin a new paragraph and insert:

"**(d) The Medicaid program may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the program would provide coverage for the same routine care costs not incurred in a clinical trial.**

(e) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the Medicaid program, including treatment rendered by participating and nonparticipating providers.

(f) This section does not require the Medicaid program to offer coverage for clinical trial services rendered by a participating

provider under the Medicaid program.

(g) This section does not prohibit the Medicaid program from offering coverage for clinical trial services by a participating provider.

(h) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

(i) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(j) This section does not create any private right or cause of action for or on behalf of any new patient against the state.".

Page 4, line 39, delete "(e)" and insert "**(k)**".

Page 5, line 10, delete "or another serious or life threatening disease".

Page 5, line 27, delete "or other serious or" and insert "**; and**".

Page 5, delete lines 28 through 42, begin a new line block indented and insert:

"**(2) that is approved or funded by one (1) of the following:**

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 6, delete lines 1 through 7.

Page 6, delete lines 32 through 42, begin a new line block indented and insert:

"**(1) The health care service, item, or investigational drug that is the subject of the clinical trial.**

(2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is

the subject of the clinical trial.

(3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

(4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.

(5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the clinical trial.

(6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.".

Page 7, delete lines 1 through 2, begin a new paragraph and insert:

"**Sec. 6. (a) A policy of accident and sickness insurance may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the policy of accident and sickness insurance would provide coverage for the same routine care costs not incurred in a clinical trial.**

(b) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the policy of accident and sickness insurance, including treatment rendered by participating and nonparticipating providers.

(c) This section does not require an insurer to offer coverage for clinical trial services rendered by a participating provider under a policy of accident and sickness insurance.

(d) This section does not prohibit an insurer from offering coverage for clinical trial services by a participating provider.

(e) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

Sec. 7. (a) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(b) This section does not create any private right or cause of action for or on behalf of any new patient against an insurer that

issues a policy of accident and sickness insurance.".

Page 7, line 11, delete "or another serious or life threatening disease".

Page 7, line 28, delete "or other serious or" and insert "**; and**".

Page 7, delete lines 29 through 42, begin a new line block indented and insert:

"**(2) that is approved or funded by one (1) of the following:**

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 8, delete lines 23 through 26, begin a new paragraph and insert:

"**(d) An individual or a group contract that provides for basic health care services may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the contract would provide coverage for the same routine care costs not incurred in a clinical trial.**

(e) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the individual or a group contract, including treatment rendered by participating and nonparticipating providers.

(f) This section does not require a health maintenance organization to offer coverage for clinical trial services rendered by a participating provider under an individual or a group contract.

(g) This section does not prohibit a health maintenance organization from offering coverage for clinical trial services by a participating provider.

(h) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating

provider at the same rate as those performed by a participating provider.

(i) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(j) This section does not create any private right or cause of action for or on behalf of any new patient against a health maintenance organization that issues an individual or a group contract.".

and when so amended that said bill do pass.

(Reference is to HB 1382 as introduced.)

BROWN C, Chair

Committee Vote: yeas 7, nays 0.